

July 23, 2021

Submitted Electronically via: www.regulations.gov

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
US Department of Labor
200 Constitution Avenue NW
Room N-5653
Washington, DC 20210

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs

Document ID number EBSA-2021-0005-0001

To Whom It May Concern:

The ERISA Industry Committee (“ERIC”) and Mercer are pleased to submit the following comments in response to the Request for Information (“RFI”) regarding new employer requirements related to reporting on pharmacy benefits and prescription drug costs.

ERIC is a national nonprofit organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. ERIC's member companies voluntarily provide benefits that cover millions of active and retired workers and their families across the country. With member companies that are leaders in every sector of the economy, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans and to lawfully operate under ERISA's protection from a patchwork of different and conflicting state and local laws, in addition to federal law.

You are likely to engage with an ERIC member company when you drive a car or fill it with gas, use a cell phone or a computer, watch TV, dine out or at home, enjoy a beverage, fly on an airplane, visit a bank or hotel, benefit from our national defense, receive or send a package, go shopping, or use cosmetics.

Mercer is a global consulting leader helping clients around the world redefine the world of work, reshape retirement and investment outcomes, and unlock real health and wellbeing for their people. In the United States, Mercer provides consulting, brokering, and actuarial services to nearly 5,000 health and benefit clients, including employers of all sizes, with varying employee demographics.

ERIC and Mercer are proud to work together in responding to the RFI on behalf of employers that provide comprehensive benefits to their employees. While we do not address every question posed in the RFI, our responses to specific questions are based on our members' and clients' current experience, benefits knowledge and expertise, and market factors.

Section A. General Implementation Concerns

Challenges in Meeting Statutory Reporting Obligations

Large employers with self-insured plans and consultants are currently unable to completely report on the required information outlined under section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) that apply to group health plans. They do not currently have access to specific information related to their formulary and prescription drug savings from their contracted pharmacy benefit manager (PBM) and medical third-party administrator (TPA). Because of this, ERIC and Mercer request that the Departments consider issuing a delay for the Final Rule, in order to give employers time to negotiate and execute new contracts that will ensure they receive the required reporting information from all third-party vendors.

Not only must employers comply with this pharmacy reporting requirement, they must also comply with the Interim Final Rule for Surprise Medical Billing, Part I, by January 1, 2022. In the preamble to the Interim Final Rule, the Departments indicated that they "intend to undertake rulemaking to fully implement these provisions, but rulemaking regarding some of these provisions might not occur until after January 1, 2022." Until rulemaking is issued later in 2022, the Departments stated they would issue "good faith compliance" standards. We request the Departments clarify what good faith compliance looks like in the interim with little or no direction. Employers, issuers, and hospitals must also comply with transparency measures that take effect for plan years starting on or after January 1, 2022.

Implementation delays have been adopted in the past where there is a new and significant administrative burden. For example, the Departments issued a one-year delay in reporting employer shared responsibility and Affordable Care Act (ACA) reporting requirements. The Departments should rely on past experience and consider issuing such a delay for the Final Rule.

Implementing a delay for the reporting requirements in this RFI will allow employers more time to collect the required data not currently available to them and make sure they are prepared for regulations that take effect on January 1. It would also give the Departments time to consider how the various new reporting and transparency requirements can be consolidated and combined to reduce duplication and unnecessary costs. However, if the Departments do not issue a delay, they can improve the ability of employers to submit the requested data by applying transparency measures to vendors such as PBMs, requiring that they share the requested information with employers and carriers, so that regulated entities can comply with this rule.

Additionally, the Departments should also consider a good faith reliance safe harbor for employers that request information from their PBMs and TPAs, but do not receive valid information for their report. The Departments should consider establishing a mechanism for determining the accuracy of the data, which should include third-party audits.

Reporting Preparation and Submission

Plans and issuers will need at least 12 months to prepare the required data for submission to the Departments and the Office of Personnel Management (OPM). Data that are readily available for employers from their PBM are currently in aggregate amounts of savings for classes of prescription drugs for rebates. This savings information is not individualized for one specific prescription drug alone. Because the reporting requires the exact savings information for each prescription drug in an employers' formulary, new means of information sharing between employers and vendors will have to be established. This information will undoubtedly be the subject of negotiations between plan sponsors and PBMs, which will affect contracts that are typically negotiated far in advance of a given plan year. As such, it is unrealistic to expect most plan sponsors to be able to produce the required data on the current abbreviated timeline.

Reporting Considerations for Self-Insured Plans

There are distinctions between self-insured plans and fully insured plans, and each will have different operating procedures in gathering the required information for their reports. Fully insured plans would benefit by relying on their insurance carrier and consolidating the information needed in the entire book of business instead of delineating each employer-sponsored plan. Collecting data can be a daunting task for self-insured employers if they have carved out their pharmacy benefit to a PBM. While the medical insurer might pay some drug claims, for example, when someone is receiving prescription drugs while hospitalized, most prescription drug claims will be paid by the PBM. Therefore, an employer that carves out its pharmacy benefit should only be required to provide the PBM data. As expressed before, self-insured plans are currently provided aggregate prescription drug rebate savings data, which does not give clarity or transparency for an employer's whole prescription drug savings. The RFI requests information employers would like to provide if they had the information, but there are other factors to take into consideration.

We find that the "health care services" category for self-insured plans is also a concern, as it seems broader than just prescription drug claims. The CAA appears to describe health care services in the context of medical claims. Again, reporting this data in a single submission will be problematic for self-insured plans that have carved out prescription drug claims to a separate PBM, which will not be able to provide this information. We urge the Departments to clarify this as the rule-making process continues and request the required data through the statutory authority described in the CAA.

The Departments have asked whether there are different considerations for reporting premiums, spending, and other data by partially insured group health plans for those that utilize stop-loss.

Stop-loss reimbursements are typically made through a separate carrier and would be difficult to consolidate with the other prescription drug data. We believe that stop-loss carriers will likely be unable to provide meaningful data to the detail that the Departments are requesting as it will take a considerable amount of time.

Reporting Tools and Systems

ERIC and Mercer believe that other pharmaceutical supply chain participants can more appropriately report most of the information requested by the Departments and OPM. It is recommended that the Departments and OPM rely on the existing Retiree Drug Subsidy (RDS) Secure Website. This system has been in place for years and can import multiple data sets from PBMs, third parties, and employers. Most if not all PBMs currently use this system for reporting plan eligibility and RDS costs. Many stakeholders are comfortable using this platform. Rather than allocating funding towards a new reporting system, utilizing, even in a modified format, a system already in place will save time, resources, and taxpayer dollars. The Departments should consider using one report format to streamline the reporting process. This way, there is less need for manual data entry, and there will be fewer opportunities for mistakes.

There is also concern from employers that the federal government might commission the creation of a new system compared to the Internal Revenue Service' (IRS) ACA Information Returns (AIR) system used to report information pursuant to the Affordable Care Act's "employer mandate" reporting (detailing the insurance coverage status of all employees and beneficiaries throughout the year). Concerns include the complexity of creating and learning a new system, requirements related to training and credentialing for reporting personnel, and generally inflating administrative costs. Those certified to report on behalf of employers would presumably be the only ones able to submit the information and data, creating complications related to employee responsibilities and adding a new layer of unnecessary complexity and room for error. For these reasons, we urge the Departments to rely upon existing data collection and reporting systems and not to create unnecessary new reporting burdens and costs.

Whatever system is used, ERIC and Mercer also encourage the Departments to allow TPAs and PBMs the ability to submit the report on behalf of employer-sponsored plans.

Section B. Definitions

Definition of Rebates, Fees, and Any Other Remuneration

The health care industry is not consistent in its definitions for terms such as "rebates". The most significant consideration regards the consistency of definitions across multiple plans and vendors. If consistency is not possible, there should be protocols to identify if a vendor's procedures vary from the standard and why. These considerations are essential because definitions of rebates can have a material impact on the financial value of the contract. If providers are not required to report on the same data points, some plan sponsors will have a less complete view of their program structure. A suggested definition of a total rebate we propose is:

"Total Rebates" will include all compensation or remuneration received directly or indirectly from a pharmaceutical manufacturer, attributable to the purchase and utilization of covered products by an eligible Participant; including all such compensation or remuneration received by Vendor's rebate aggregator or GPO arrangement. Compensation includes but is not limited to discounts; credits; rebates, regardless of how categorized; fees (including formulary management or placement fees); educational grants received from manufacturers in relation to the provision of utilization data to manufacturers for rebating, marketing, and related purposes; market share incentives; commissions; data fees; manufacturer administrative fees; and price inflation protection payments.

We believe that service fees – ad hoc fees paid by the plan sponsor for optional elected services such as maintenance of a custom formulary – do not need to be included in the rebate definition but should be included as a data point. As with rebates, if data fees (which can be material) are not included, then the plan sponsor will have an incomplete view of program costs.

Regarding additional fees, if the intention is to have the reporting capture a complete view of plan costs, including costs of administration and other optional costs, then all fees should be included. Those fees that are mandatory and embedded in plan administration should be noted as such. Those fees that are optional (at the plan sponsor's discretion) should also be included but indicated as optional or at the plan's discretion.

We would also like to address copay assistance cards or coupon cards, as they have become a significant factor in the rebate conversation in recent years. In some ways, coupon cards are a direct-to-patient "rebate" that pharmaceutical manufacturers generate. Over the last several years, the "gross to net bubble", the difference between gross list prices and net prices, grew. The difference between gross and net prices is the pharma-provided rebate. The rebate makes the product lower cost to the plan and may influence PBMs to prefer one similarly effective product over another.

In most cases, the plan sponsor retains the rebate, with some portion going to the PBM in certain situations. In highly competitive classes with no or few generic products, the rebate may be 40 to 60 percent of the average wholesale price (AWP) "list price". The growth in coinsurance and high deductible health plan (HDHP) designs means that the member's cost share does not include the significant "buy down" of the rebate when filling high-cost prescriptions. In some cases, this may mean that patients may not fill the prescription, or may elect to get a sub-therapeutic partial dose. A recent IQVIA study¹ showed that 49 percent of member out-of-pocket (OOP) costs were associated with just 9.5 percent of dispensed prescription drugs. The plan design for these prescriptions was a coinsurance or HDHP as opposed to a flat copay. In many of these cases, members use copay cards to get the prescription at a lower price. For some

¹ IQVIA Institute. "Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicines" August 4, 2020. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

medications, the member may go “off the plan” and use third-party providers like GoodRx. Therefore, the ability to capture and report on the use of copay cards may help plan sponsors assess how their cost-sharing affects members. However, the ability to capture their use may vary by PBM and carrier, who may be the best to answer this request. The Departments should consider requesting PBMs to report on volumes of sales and rebates they are receiving as they have the information. Ultimately, the most accurate data about copay assistance cards would come from the pharmaceutical companies that pay those expenses and administer the systems – they know exactly how much is being paid, on which beneficiaries’ behalf, to which plans, for which products. We encourage the Departments to consider going directly to the source to obtain this data.

Regarding accumulator programs, many PBMs and providers offer these programs that prevent coupon card payments from counting toward the member’s deductible and out-of-pocket limits. In the absence of these programs, the pharmaceutical company copay assistance (which is a de facto direct-to-member rebate) would count toward the deductible/out-of-pocket maximum even though the member does not pay it. While this seems counter to plan design goals, the reality is that third-party surveys show that once members’ out-of-pocket costs are \$50 or more per prescription, adherence rates drop.² Since it appears many PBMs can report on this activity, we suggest that this information be included in reporting so its impact can be assessed on both an individual plan sponsor and global basis.

Definition of Pharmacy

ERIC and Mercer believe that any entity that dispenses a prescription to a member that is adjudicated by the plan should be considered a “pharmacy” and included in reporting. This definition would consist of retail, mail, specialty, and 340B “contract” pharmacies. Note that various third-party claims like GoodRx are adjudicated “off the plan” and are not reported.

Drug pricing methodologies vary dramatically based on the point of service and treatment administration. Under most PBM plans, the standard method is to report on drug use under AWP as the typical benchmark, even though there are some problems associated with AWP (for instance, this information may not be broadly available to plan sponsors without a subscription to a third-party data warehouse). Despite this concern, tracking overall PBM spend through current reporting is relatively easy. However, this does not mean that plan sponsors know the PBM or carrier’s acquisition cost. The reporting provides plan and member cost, not acquisition cost. Various treatment venues like outpatient hospitals and physician offices (for infused medications) present significant reporting challenges.

In most cases, the submitted claim and reporting is a “bundled” number that includes drug cost, administration fees, and treatment fees such as drug administration. The bundled approach makes it challenging to identify individual components such as drug price. Many high-cost claims (such as the new drug Aduhelm) are infused and typically managed under the medical plan, not the

² Ibid.

PBM. Understanding actual underlying drug costs for these claims will continue to be a challenge if this current reporting methodology does not change.

Definition of Prescription Drug

There are growing differences in how PBMs are defining prescription drugs. We suggest that reporting capture the full scope of plan sponsor payments under the plan. So, the definition should be for a “prescription claim” rather than a “drug” as some items paid under the plan are not drugs but are covered items such as diabetic test strips. A suggested definition of “claim” we propose is:

“Claim” means any electronic or paper request for payment or reimbursement arising from retail participating pharmacies, mail order pharmacies and specialty pharmacies, providing Covered Products to a Plan Participant processed under this Agreement in accordance with the Client's Plan. For purposes of this “claim” definition, “covered products” shall also include products that are approved to be covered through the bidder's review processes (e.g., PA or medical exception process) or through the appeals process (including external appeals).

A suggested definition of “covered product” we propose is:

“Covered Product” means prescription drugs, over-the-counter medications and other services or supplies that are covered under the terms and conditions set forth in the description of the client's plan.

No matter the definitions the Departments decide, we urge you to consider the amount of reporting you would like to receive and what would be most helpful.

Definition of Therapeutic Class

The definition of therapeutic class is well-established, with four components making up the definition of therapeutic class. Those four variables are chemical structure, mechanism of action, mode of action, and disease/condition treated. The classification does not require proprietary software, and most plans use pharma-developed classifications. We suggest that the Departments make use of this widely-accepted definition.

Definition of Health Care Services

As stated earlier, this category seems to be broader than just prescription drug claims. This definition is a concern, particularly for self-insured plans, which would be burdened to search, compile, and provide copious amounts of data. We request that the Departments ensure that a narrow and specific definition is used to keep reporting manageable.

Section C. Entities That Must Report

Special Considerations for Group Health Plans

Individual Coverage Health Reimbursement Accounts (ICHRA) and account-based plans do not track reimbursements by specific type of drug. It will be an almost insurmountable challenge for these plans to report, for example, the top 50 brand name drugs. We request the Departments and OPM consider an exemption for all HRAs (including HRAs that are integrated with other group health coverage, excepted benefit HRAs and retiree HRAs), health FSAs, and HSAs, as employers will rely upon data from vendors: carriers, PBM, and point-solution vendors. The Departments should also consider good faith compliance for employers obtaining this information from their vendor, which is currently unavailable to them. Again, without such protection or help for employers in retrieving the needed information, reports will be incomplete and unhelpful.

Functionally, these accounts are financing mechanisms, not insurance plans. Each of the above (ICHRA, HSA, HRA, FSA) would not generally be used outside of the auspices of an actual insurance plan, be it self-insured or fully-insured. Those plans would themselves already be subject to reporting. As such, it would be unnecessary, duplicative, and likely impractical to require separate reporting for the accounts. In addition, each of the above account for only a very small portion of the overall spend related to prescription drugs.

Self-Insured Plans and TPAs

The Department should expect that self-insured and partially insured group health plans will contract with TPAs or other service providers to submit the required data on their behalf. Medical TPAs and PBMs maintain this data, and plan sponsors have little to no access. While reporting mechanisms are in place in most cases, significant revisions to existing contracts and systems are likely needed in order to meet the specific requirements in the CAA. It is recommended that good faith compliance relief be provided to plan sponsors that reach out to their TPA but do not receive the correct information.

Further, we urge the Departments to consider mass collection of data directly from carriers and TPAs. Significant efficiencies and savings could be achieved by collecting the bulk of needed data directly from the entities that currently possess it, who could (in most cases) report on behalf of many employers at once. Because the intent of the CAA was to efficiently collect data rather than unnecessarily burden employers, such an approach warrants serious consideration.

PBM Roles

PBMs have an essential role in furnishing the necessary information to plan sponsors and issuers. Most plan sponsors rely on their PBM or carrier for reporting today, as the PBMs adjudicate the claims and access the required information. Very few employers have the infrastructure to populate the required reports, so they rely on their vendors – and likely will depend upon them in order to comply with the CAA reporting requirements as well. In most cases, PBMs will have

adequate detail to provide most data elements in the requested reporting for pharmacy. Typically, they will not have information on spending in non-pharmacy areas and may not have information on employee contributions or plan design not directly related to the pharmacy benefit. This information would need to come from the plan sponsor and medical carrier. However, a PBM could easily partner with a carrier to complete most of the required reporting, and indeed, in many cases the PBM is part of an enterprise that includes the carrier servicing the same client.

At this point, carriers and PBMs indicate they will support required reporting. Few have indicated what additional fees they will charge for doing so, though. Many PBMs may report rebates but may not note total received rebates from pharmaceutical companies but rather rebates transferred to the plan (not including any monies retained by the PBM). The new reporting does require some additional administration from the various vendors, so they are charging their customers for this additional service.

As stated above for TPAs and carriers, it may be most efficient for the Departments to collect much of the data directly from the entities that possess it. In this case, with three PBMs administering more than 75 percent of the markets, each PBM could report on behalf of a vast array of employers.

Section D Information Required to be Reported

Determining 50 Brand Drug Prescriptions

The report should include information on spend, number of claims, and days' supply. In order of priority, the reporting should consist of:

- Total plan spend on that drug
- Number of prescriptions
- Number of utilizing members
- Days' supply

PBMs should then report on this data easily as most of their current standard reporting includes this data today.

50 Brand Drug Prescriptions and Plan Expenditures

Cost increases to a plan pursuant to prescription drugs are typically a combination of unit cost increases, and utilization increases. Therefore, reporting should show a total cost increase and the various components of that cost increase, including unit cost increase and utilization increase. Utilization increase could include an increased number of prescriptions for existing patients, as well as prescriptions filled by new patients (keep in mind that this would include both members new to the plan, and members new to a given treatment based on a new diagnosis). The reporting should show the actual increase in dollars and a percentage increase relative to the previous plan period. If possible, the reporting should show the previous year and current year percentage of

drug spending by each of the 50 drugs. Note that PBMs provide reporting like this to plan sponsors today. The report's primary focus allows the plan to determine the key driver of increased costs by a drug in its plan. We would expect that drugs in more prevalent disease states like diabetes and hypertension would be more significant contributors. However, an individual plan sponsor may have utilization due to their population demographics with high spending in less common disease states. This information would allow a plan sponsor to focus their efforts on cost management more effectively.

Prescription Drugs and RxNorm Concept Unique Identifier (RxCUI)

For this process to work as efficiently and transparently as possible, existing classifications used by PBMs currently, such as the National Drug Code Directory, should also be used for this reporting. Inserting a new classification system would require all stakeholders to adapt to the new system, and there may not be a complete crosswalk from existing classifications to RxCUI. Speaking more broadly to “health care services” reporting, depending on the final rules and definitions of this requirement, further consideration may be needed to determine the classification of drugs and health care services.

25 Highest Drug Rebates and Other Remuneration

The reporting should include total rebates released, the number of prescriptions associated with the released rebates, and number of units associated with the rebates. Note that today PBM contracts and reporting do not identify rebate guarantees or payments at the drug level. PBM reporting and contracts are done at the aggregate level. In most cases, the plan sponsor does not know what assumptions regarding utilization the PBM makes in setting rebate guarantees. Due to the variation in the amount pharmaceutical companies reimburse, it is strongly recommended that rebates and other remuneration are reported as a percent of the total cost of the drug – in addition to the actual dollar amounts.

Rebate Impact on Premiums and Out-of-Pocket Costs

In most cases, plan sponsors use rebates as a cost offset in setting budgets and member cost-sharing. Additionally, close attention should be paid to future rebate projections. Rebates are tied to “list price” of the drug, and list price increases have, in aggregate, been in the mid-single digits in the last few years. This fact may be one of the drivers for various pharmacy providers starting new Group Purchasing Organizations to pool buying power for increased leverage.

The question of member out-of-pocket costs (OOP) related to rebates is a critical policy issue. On the one hand, some observers feel that patients who use very high-cost drugs and are on coinsurance or high deductible health plans (i.e., plan design is not a copay structure) should receive all or part of the rebate on that drug. Only seven to eight percent of total prescription drugs generate 100 percent of rebates, and these funds are typically used to reduce costs for all enrollees. On the other hand, if all or part of rebates were paid only to the members utilizing those drugs, then overall plan costs would increase for the plan, and increased contributions for

all members would be likely. Most PBMs have built functionality to pay all or part of rebates to members (as opposed to plan sponsors). However, plan sponsors must agree to re-direct rebates to members, with most plan sponsors utilizing the funds to lower employees' premiums.

The Departments' final reporting should make clear that directing rebates to the patient filling the prescription would have multiple impacts. First, members utilizing rebate generating drugs would have savings, but aggregate plan costs would increase. The plan sponsor would either need to absorb those costs or increase plan contributions to all plan participants. Some current participants could elect to get coverage elsewhere, which could further affect underlying plan financials as these members would likely be low utilizers. Second, the rebate dollars come from the pharmaceutical companies, but are based on the plan sponsor's utilization of those drugs. The plan sponsor is the ERISA fiduciary and has ultimate responsibility for determining what is best for the plan. The Departments must endeavor to make this clear in reports released to the public.

Rebate Collection

The Departments and OPM should use the same categories and sub-categories as the PBM Transparency for Qualified Health Plans to promote consistency.

Payment Flow

Generally speaking, payments in the pharmacy space are going from pharmaceutical companies to other supply chain entities like PBMs and carriers. Therefore, it is unlikely that any payments from PBMs to Pharma need to be included in reporting. One exception to this might be fees paid by pharmacies back to a PBM. The Departments should collect this information either from pharmacies or from the PBMs, and the info should be attributable to the plans for which fees were paid, in order to determine if these fees are affecting plan outlays.

Section E Coordination with Other Reporting Requirements

Removing Other Reporting Requirements

It is our belief that there is overlap between this RFI, and other reporting requirements, including the Transparency in Coverage Rule. We encourage the Departments to initiate an audit of collection activities and work toward the goal – based on the Paperwork Reduction Act – of minimizing the burden of reporting for employers, PBMs, TPAs and the federal government.

Section F Public Report and Privacy Protections

Data Collection Time Frame

Most ERIC member companies operate on a calendar year basis. However, some plans operate differently on a fiscal plan year that does not match up with the calendar year. Therefore, the Departments and OPM should consider allowing plans the flexibility of reporting based upon either the plan year or the calendar year. In addition, the CAA requires reporting on the “previous plan year.” The Departments should consider defining this term in such a way that employers have a period of time after the plan year ends in which to report the data. For example, providing a six-month deadline after the plan year ends would likely provide sufficient time to ensure accurate and complete reporting.

Comparative Analysis of Report

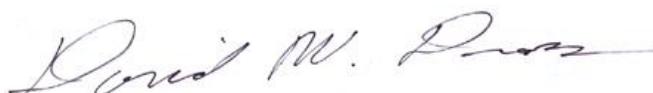
The Departments and OPM should consider including a comparative analysis of prescription drug costs for plans and issuers relative to costs under Medicare, as well costs paid in other countries, to understand prescription drug prices in the United States. To put this information into context, it may also help to include information about the amount pharmaceutical companies invest in research and development in a given year, as well as the amount spent on advertisements and marketing for drugs in the US.

Conclusion

Thank you in advance for considering these comments. Please do not hesitate to contact us with any questions or if ERIC and Mercer can serve as a resource on these very important issues. For additional information, please contact [James Gelfand](#) at ERIC, or [David Dross](#) at Mercer.



James Gelfand
Senior Vice President, Health Policy
The ERISA Industry Committee



David Dross
Managed Pharmacy Practice Leader
Mercer